

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
THIS RELATES TO)	Civil Action No. 01-CV-12257 PBS
STATE OF MONTANA v. ABBOTT LABS.,)	Judge Patti B. Saris
INC., et al.,)	Chief Magistrate Judge Marianne B. Bowler
02-CV-12084-PBS)	

**LOCAL RULE 56.1 STATEMENT OF DEFENDANTS
BRISTOL-MYERS SQUIBB COMPANY ONCOLOGY THERAPEUTICS
NETWORK CORP. AND APOTHECON, INC.**

Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corp. (“OTN”) and Apothecon, Inc. (collectively “BMS”) respectfully submit this Local Rule 56.1 statement in support of their motion for summary judgment.¹

The Parties

1. At all relevant times, plaintiff Montana Medicaid has set the reimbursement rates for drugs for Medicaid beneficiaries, with the approval of CMS and its predecessors. (Mont. Code Ann. § 53-6-113; Administrative Rules of Montana 37.86.1101;

¹ BMS also joins in the Joint 56.1 statement of the defendants. BMS relies, in part, on the Trial record in the Class 2 and 3 trial. Class 2 and 3 trial testimony is cited by witness’s last name, date and transcript page number (e.g., Smith xx/yy/zz Tr. 123). References herein to the witness’s written direct testimony includes last name, the abbreviation “Aff.” and a paragraph number, (e.g., Smith Aff. ¶ 1). Citations to deposition transcripts are in the same format as trial testimony, but include the abbreviation “Dep.” after the witness’s name instead of “Tr.” References to “DX” or “PX” with a document number are references to trial exhibits in evidence. The Declaration of Steven M. Edwards, dated February 8, 2007 (“Edwards Decl.”), is proffered for the limited purpose of placing certain additional record evidence before the Court. The expert declaration of Dr. Gregory K. Bell, Ph.D., dated February 8, 2007 (“Bell BMS MT Decl.”), is proffered for the limited purpose of providing background information and presenting an analysis of the relationship of BMS transaction prices to list prices.

37.86.1105, annexed to the Edwards Decl. as Ex. A; Notice of Approval of State Plan Material (Montana), TN-008 (approved Dec. 19, 2000), annexed to Edwards Decl. as Ex. B.)

2. BMS is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. (State of Montana's Second Amended Complaint ("Montana SAC") ¶ 61.)

3. OTN is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, California. (Id. ¶ 62.) Defendant OTN is the general partner of an operating entity, also known as OTN. (Akscin Aff. n. 1.) All references to "OTN" include the operating entity.

4. Apothecon is a Delaware corporation with its principal place of business located in Princeton, New Jersey. (Id. ¶ 64.)

BMS Pricing

5. Five BMS oncology drugs are at issue on this motion: Blenoxane, Cytoxan, Paraplatin, Taxol and Vepesid ("BMS Oncology Drugs").² (Montana Declaration of Raymond S. Hartman, dated June 13, 2006 ("Hartman MT Report"), Tables 1 and 2.)³

6. Also at issue on this motion are certain BMS self-administered drugs: Avapro, Buspar, Cefzil, Coumadin, Glucophage, Glucophage XR, Glucovance, Monopril, Monopril HCT, Plavix, Serzone, Tequin and Videx. (Hartman MT Report, Table 3, annexed to Edwards Decl. as Ex. E.) (All the BMS drugs at issue are referred to herein as "the Subject Drugs")

² Although the Montana SAC purports to assert claims with respect to Etopophos and Rubex, Dr. Hartman did not find liability, damages or penalties for these drugs. (Bell BMS MT Decl. ¶ 6.)

³ These tables are annexed to the Edwards Decl. as Exs. C & D, respectively.

7. For the Subject Drugs, BMS established a list price, or WLP, at the time it launched the product. (Declaration of Zoltan Szabo in Support of Defendant Bristol-Myers Squibb Company's Memorandum in Opposition to Plaintiffs' Motion For Class Certification ¶ 2 ("Szabo Decl."), annexed to Edwards Decl. as Ex. F; Szabo Aff. ¶ 7; Pasqualone Aff. ¶ 13.)

8. The WLP appears on invoices to wholesalers, and most of the sales to customers when a product is protected by a patent are within 5% of list price. (Szabo Decl. ¶¶ 2-3.; Bell BMS MT Decl. ¶¶ 9a, 13-15, 23-24, 27, Ex. F.)

9. While a drug is protected by patent, BMS may periodically raise the WLP for a drug; but it does not do so unless it believes that it can obtain sales at the new price. (Szabo Decl. ¶ 3; Pasqualone Aff. ¶ 14; see also Bell BMS MT Decl. ¶¶ 9b, 10, 19.)

10. After a drug loses its patent protection, BMS generally does not make further changes to its list price. (Szabo Decl. ¶ 3; Pasqualone Aff. ¶ 18; Pasqualone 12/06/06 Tr. 7; Marre 11/14/06 Tr. 133, 154-155; Szabo Aff. ¶ 11; Bell BMS MT Decl. ¶¶ 9b, 10, 19.)

11. From time to time, BMS offers discounts and rebates to downstream customers in order to meet competition. (Szabo Decl. ¶ 4; Bell BMS MT Decl. ¶¶ 10, 12, 20-22, Ex. E.)

12. In the case of a discount, BMS will enter into a contract with a customer such as physician, hospital or HMO which entitles the customer to acquire the drug at a discounted price. (Szabo Decl. ¶ 4; Bell BMS MT Decl. ¶ 21.)

13. BMS will sell the drug to the wholesaler at the list price; the wholesaler will sell the drug to the customer at the discounted price; and then the wholesaler will receive a "chargeback" from BMS that makes it whole. (Szabo Decl. n.1; Bell BMS MT Decl. ¶ 21.)

14. In the case of a rebate, the customer will receive money some time after the original sale based on the volume of purchases. (Szabo Decl. ¶ 4 & n.1; Bell BMS MT Decl. ¶ 29-33.)

15. Charles River Associates (“CRA”), an economic consulting firm, has performed an analysis to determine the extent to which the drugs at issue were sold within 5% of list price. (Bell BMS MT Decl. ¶¶ 9a, 13-15, 23-24, 27, Ex. F.) For the oncology drugs at issue, that analysis demonstrates that, during the period 1993 through 2002, 86.2 % of BMS’s net revenue for the Subject Drugs was achieved in transactions at prices that were within 5% of WLP. (Bell BMS MT Decl. ¶ 13, Ex. F.) Generally, while the products were protected by patents, more than 95 % of net revenue was attributable to sales that were within 5% of WLP. (Bell BMS MT Decl. ¶ 14, Ex. F.) When the products became subject to multi-source competition, that percentage remained substantial: 27.4 %. (Bell BMS MT Decl. ¶ 15, Ex. F.)

16. For the remaining self-administered drugs at issue in this case, 90.4 % of BMS’s net revenue -- for all classes of trade -- came from sales within 5% of WLP during the period 1993 through 2002. (Bell BMS MT Decl. ¶ 23, Ex. F.) While those drugs were protected by patents, 90.3% of BMS’s net revenue came from sales within 5% of WLP. (Bell BMS MT Decl. ¶ 24, Ex. F.) After generic competition, the percentage of net revenue achieved in sales at or near least price actually increased to 91.3%. (Bell BMS MT Decl. ¶ 24, Ex. F.)

BMS Price Reporting

17. BMS reports its list prices to industry publications such as Red Book, First Data Bank and MediSpan. (Kaszuba Aff. ¶ 3; Kaszuba 11/13/06 Tr. 52, 109; Szabo

Decl. ¶ 5; Rogers Aff. ¶¶ 1-2.) Those list prices are the list prices that appear on BMS' invoices to wholesalers. (Szabo Decl. ¶ 2; Rogers Aff. ¶ 4.)

18. BMS has never communicated AWPs to the publications. (Kaszuba Aff. ¶ 6; Szabo Aff. ¶ 6; Kaszuba 11/13/06 Tr. 110, 113; Szabo Decl. ¶ 6.)

19. The publications calculate AWPs by multiplying the list price by a mark-up factor ranging from 20% to 25%. (Kaszuba 11/13/06 Tr. 59, 120-21; DX 2611 at BMS/AWP/00018649, DX 2616; see also Szabo Decl. ¶ 6.)

20. BMS does not control the mark-up factor that the publications use to calculate AWPs. (Morgan Dep Tr. 230; Kaszuba Aff. ¶ 6; Kaszuba 11/13/06 Tr. 58, 110-13; DX 1137; DX 2587/PX 196 at BMS/AWP/00442095; DX 2588/PX 187 at BMS/AWP/01109782; DX 2589/PX 189 at BMS/AWP/01088211.)⁴

21. While once -- in 1992 -- BMS asked the publications to change their mark-up factor from 20.5% to 25%, only Red Book acceded to that request; First Data Bank and MediSpan refused. (Kaszuba Aff. ¶ 13; Kaszuba 11/13/06 Tr. 60, 114; DX 2552; DX 2553; DX 2554; Szabo Aff. ¶ 6; Szabo Decl. ¶ 6.)

22. In 2002, First Data Bank unilaterally changed the mark-up factor for all drugs to 25%. (Kaszuba Aff. ¶ 15; DX 2588/PX 187 at BMS/AWP/01109782; DX 2589/PX 189 at BMS/AWP/01088206.)

23. Various documents further confirm that BMS did not control AWPs. (See DX 1522; DX 2545; DX 2554; DX 2585 at BMS/AWP/001510398; DX 2588/PX 187 at

⁴ Excerpts of the deposition of Patricia Kay Morgan, taken on January 11-12, 2005, are part of the Class 2 and 3 trial record (See Appendix BMS' Post-Trial Proposed Findings of Fact, dated January 19, 2007 ("BMS Findings of Fact."))

BMS/AWP/01109782; DX 2587/PX 196 at BMS/AWP/00442095; DX 2589/PX 189 at BMS/AWP/01088211; DX 2595 at BMS/AWP/00059757.)

24. Beginning in 1999, BMS began to include language in its communications to publications notifying them that some customers receive manufacturer discounts or rebates that are not reflected in BMS's list prices. (Szabo Decl. ¶ 5; Kaszuba Aff. ¶ 7; Kaszuba 11/13/06 Tr. 127-28; Szabo Aff. ¶ 6; DX 2627 at FDB-AWP-18630.)

25. An example shown to Kay Morgan of First Data Bank at her deposition states: "Wholesale and Direct List Prices, including those for the products listed herein, may not reflect actual Bristol-Myers Squibb sale prices. Certain multisource products are always sold at lower special offer prices. All products may be subject to negotiated discounts, rebates and chargebacks." (Morgan Dep. Ex. 41, annexed to Edwards Decl. as Ex. G.) This disclosure had no impact on the way the Publications calculated AWPs. (Kaszuba Aff. ¶ 7; Kaszuba 11/13/06 Tr. 127-28; Szabo Aff. ¶ 6; Morgan Dep. Tr. 227.)

BMS Marketing

26. Plaintiffs took the depositions of eleven BMS sales representatives in the MDL class action and this action.⁵

27. The testimony of those witnesses was uniform and consistent: the BMS sales representatives who sold physician- administered oncology drugs emphasized the therapeutic attributes of the drugs, but when asked questions about reimbursement they

⁵ Deborah Ekborg, June 1, 2006, Charles Tabano, August 23, 2006, Marsha Peterson, April 13, 2005, Douglas Soule, April 26, 2005, Gena Cook, April 28, 2005, Greg Keighley, July 2, 2005, Fran M. Morrison, July 27, 2005, Raul Armand, July 29, 2005, Joe Petrella, July 29, 2005, Dana Faulkner, August 16, 2005, Thomas Liptak, August 17, 2005. The complete deposition transcript of Ekborg and Tabano are annexed to the Edwards declaration as Exs. H & I, respectively. Testimony from the other sales representatives are part of the Class 2 and 3 trial record -- Peterson and Soule testified at trial on December 8, 2006 and excerpts of the Armand, Cook, Faulkner, Keighley, Liptak and Morrison depositions were annexed to the Appendix to the BMS Findings of Fact.

responded with truthful information. (Pasqualone 12/6/06 Tr. 13, 15; Pasqualone Aff. ¶ 42; Soule 12/08/06 Tr. 56-59; Soule Aff. ¶¶ 5, 9; see also Peterson Aff. ¶ 9; Peterson 12/08/06 Tr. 87-88; DX 2605 (the same policy applied to OTN sales representatives); Armand Dep. Tr. 42-43, 91-93; Cook Dep. Tr. 98-99; Faulkner Dep. Tr. 32, 42, 67; Keighley Dep. Tr. 49-51, 69-70, 92-94, 101, 166-167; Liptak Dep. Tr. 55-56, 65-66; Morrison Dep. Tr. 95-97.)

28. In 2001, BMS formalized that policy in a memorandum from Ed Penick to all U.S. Sales and Marketing Personnel. (PX 223.) This policy was enforced. (Pasqualone 12/06/06 Tr. 15, see also Soule 12/08/06 Tr. 58-59; Peterson 12/08/06 Tr. 87-88; DX 2605.) There is no evidence that BMS “manipulated” AWPs and then told its sales representatives to promote the spread as a reason to purchase its products.

29. As to the sale of self-administered drugs (called “primary care” drugs by BMS) to physicians, BMS sales representatives sell the therapeutic benefits of those drugs to physicians. (Ekborg Dep. Tr. 48-49; Tabano Dep. Tr. 37-41.) BMS representatives do not speak to physicians regarding the pricing for BMS products, including the AWP for those products. (Ekborg Dep. Tr. 17-18, 35, 55, Tabano Dep. Tr. 41-45, 52-53.) Nor do BMS sales representatives discuss price with retail pharmacies. (Ekborg Dep. Tr. 48-49; Tabano Dep. Tr. 42-45.) BMS sales materials used with physicians for primary care drugs do not contain information about AWP. (Tabano Dep. Tr. 38-39, 42-45, 94, 97-102; Ekborg Dep. Tr. 35, 48-49.)

30. BMS sales representatives had no authority to provide discounts or negotiate prices. (Armand Dep. Tr. 42-43, 91-93; Cook Dep. Tr. 98-99; Faulkner Dep. Tr. 32, 42, 67; Keighley Dep. Tr. 49-51, 69-70, 92-94, 101, 166-167; Liptak Dep. Tr. 55-56, 65-66; Morrison Dep. Tr. 95-97.)

31. BMS does not give material discounts or rebates to pharmacies for its self-administered drugs. (Bell BMS MT Decl. ¶¶ 9g, 18, 20-21, 37, 39(b).)

32. As to brand name drugs, pharmacies have no control over the prescription and must dispense the drug prescribed by the physician. (Bell BMS MT Decl. ¶ 39b; Rosenthal 11/15/06 Tr. 115; Addanki 12/13/06 Tr. 65.)

33. As to brand name drugs sold through pharmacies, physicians make clinical decisions to prescribe the drug to their patients and have no economic interest in the transaction. (Rosenthal 11/15/06 Tr. 115; Addanki 12/13/06 Tr. 65; Bell BMS MT Decl. ¶¶ 9(f), 39b.)

Montana Medicaid and Medicare were aware of the spreads for BMS drugs

34. The record demonstrates that Medicare and Montana Medicaid were aware of the spreads for specific BMS drugs. (See, e.g., DX 1053; DX 1075; DX 2648 at C-2, C-3; DX 2641; DX 1881; DX 2631.)

35. Montana Medicaid received substantial rebates on the BMS Subject Drugs. (Bell BMS MT Decl. ¶ 34, Exs. I & J.)

36. Beginning in October 2001, Montana Medicaid received ASPs for various drugs from Bayer, TAP and AstraZeneca. (Buska Dep. Tr. 509, annexed to Edwards Decl. as Ex. J; see also Buska Dep. Ex. 053, annexed to Edwards Decl. as Ex. K.) Despite knowledge that those ASPs were uniformly well below published AWPs, the State did not change its reimbursement for those companies' drugs. (Montana's Response to Bayer's

Interrogatory No. 1, annexed to Edwards Decl. as Ex. L at 5; MT 38330, annexed to Edwards Decl. as Ex. M; Buska Dep. Tr. 527, 563-564, annexed to Edwards Decl. as Ex. J.)

Dated: Boston, Massachusetts
February 8, 2007

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Lyndon M. Tretter, certify that on February 8, 2007 a true and correct copy of the foregoing Local Rule 56.1 Statement of Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corp. and Apothecon, Inc. was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter

Lyndon M. Tretter